

Application No. 10/649,457

Reply to Office Action

*REMARKS/ARGUMENTS**Requirement for Restriction and Election of Species*

The Office Action has set forth a restriction requirement. Applicants elect, with traverse, the claims of Group II (claims 1-10, 13-20, and 21). As such, claims 11, 12, and 22-41 are withdrawn. Applicants understand that claims 1-10 and 21 link the claims of Groups I and II. Thus, upon allowance of the linking claims, the restriction requirement as to the linked inventions will be withdrawn, and any claims depending from or otherwise requiring all of the limitations of the allowable linking claims will be rejoined and examined.

The Office Action also has set forth an election of species requirement. Applicants elect, with traverse, protective antigen as the exotoxin, and a lysosome pathway as the subcellular sorting pathway. Claims 1-10 and 13-21 read on the elected species. Upon allowance of a generic claim, Applicants understand that the Patent Office will consider the other claimed species.

Reconsideration of the requirements for restriction and election is respectfully requested for the reasons discussed below.

Discussion of the Restriction Requirement

There are two separate criteria for a proper requirement for restriction between patentably distinct inventions: (i) the inventions must be independent or distinct as claimed, and (ii) there must be a serious burden on the Examiner if restriction is not required. Both of these criteria must exist for a restriction requirement to be proper, and "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (M.P.E.P. § 803).

Here, the Office Action does not indicate, let alone establish, that there would be a "serious burden" on the Examiner to examine all of the groups of claims at the same time. The fact groups of claims may be drawn to distinct or independent inventions, as the Office Action alleges, does not necessarily mean that examining the groups of claims concurrently would place a "serious burden" on the Examiner. Applicants respectfully submit that the restriction requirement as between claims of Groups I, II, III, and IV is improper because the

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nature of the claims is such that any burden encountered in searching the groups together would, at most, be slight (and certainly not "serious"). In this regard, independent claim 1 is common to both Groups I and II, and the claims of Groups III and IV are directed to methods of using a gene transfer vector identical to that described in claim 1. Thus, if the composition claims of elected Group I (and Group II once the claims are rejoined) are determined to be patentable, the use thereof must be novel and unobvious (i.e., the subject matter of the claims of Group III, and IV, respectively). As such, any search and consideration of the claimed subject matter of Group I will necessarily overlap the search and consideration of the claimed subject matter of Groups II-IV.

Accordingly, there would appear to be sufficient similarity between the claims of Groups I-IV to allow for the search and examination of the subject matter of claims 1-41 at the same time without a "serious burden" being placed on the Examiner. Applicants, therefore, respectfully request withdrawal of the Restriction Requirement, and respectfully submit that the claims of Groups I-IV should be examined together.

Discussion of the Election of Species Requirement

The Office Action's requirement for election of species is not well founded. While the Office Action alleges that claims 2 and 23 and claims 7 and 28 recite patentably distinct species, Applicants submit that, even if the claims are directed to independent and distinct species, it would not be unduly burdensome to search all of the alleged species together. In this respect, a search of the invention wherein the gene transfer vector encodes an immunogenic portion of one or more *Bacillus anthracis* exotoxins likely would identify art disclosing all of the *B. anthracis* exotoxins (i.e., protective antigen (PA), edema factor (EF), and lethal factor (LF)). Similarly, a search of the invention wherein the gene transfer vector comprises a heterologous sorting signal that directs the exotoxin to a subcellular sorting pathway likely would identify art disclosing numerous such pathways, including extracellular pathways, cytoplasmic pathways, cell membrane pathways, lysosome pathways, endoplasmic reticulum pathways, and degradative pathways.

Accordingly, the examination of the species set forth in the Office Action would involve overlapping searches and certainly would not be unduly burdensome. In the absence of such a "serious burden," the election of species requirement is improper even if the alleged

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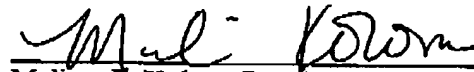
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species are patentably distinct. Applicants, therefore, respectfully request withdrawal of the election of species requirement.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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